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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097261,068	03/02/99	MAHANT	V

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EXAMINER
GABEL, G

ART UNIT	PAPER NUMBER
1641	3

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/261,068

Applicant(s)

Mahant et al.Examiner
Gallene R. GabelGroup Art Unit
1641☐ Responsive to communication(s) filed on _____.☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-21 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

✓ Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath or declaration does not specify the filing date of a foreign application. A new oath or declaration is required in the body of which the present application should be identified by application number and filing date.

Drawings

✓ 2. The drawings in this application are objected to by the Draftsperson (see PTO-948 attached) Correction is required. However, formal correction of noted defect can be deferred until application is allowed by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indeterminate in scope in reciting "each of the additive, the particles, and the cells having a substantial binding to another of the additive, the particles, and the cells to produce a cell containing network" because it does not specifically define the structural relationship between the cells, the additive, and the particles. Eg. do the three elements form a complex. Furthermore, claim 1 is indeterminate in scope by failing to specifically define what is encompassed by the terms "additives" and "particles". Also, claim 1 does not define the role of the "additive" or the "particle". Moreover, claim 1 is indefinite in reciting "separating the network from the substantially cell depleted portion at least in part using a magnetic force" because it does not specify what other factor, if any, effects the separation of the network from the cell depleted portion.

Claim 4 is indefinite in reciting "the vessel has at least one flexible wall". The term "flexible" does not have a comparative basis for defining its metes and bounds.

Claim 6 is unclear in reciting "the particles having a mean volume of between about $5 \times 10^{-24} \text{ m}^3$ to about $5 \times 10^{-6} \text{ m}^3$ " since it does not specifically define composition of the particle. Eg. whether the particles are in solid or liquid phase.

Claim 7 is indefinite in reciting "wherein the substantial binding of the particles results at least in part from the particles having a coating" because it does not specify what other factor

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effects the substantial binding of the particles. See also claim 11 as applied to the substantial binding of the additives.

Claim 10 is indeterminate in scope in reciting "comprises a polymer" because it does specifically define what is encompassed within the composition of the polymer.

Claim 12 is indefinite by failing to recite active, positive statements by reciting "the primary has a substantial binding to the surface component of the cells, and the secondary antibody has a substantial binding to the primary antibody". Eg. if applicants mean to imply that the primary antibody substantially binds to the surface of the component and so on, then applicants should positively and actively state so. Furthermore, the claim is confusing in reciting "comprises a primary and a secondary antibody" since in claim 1 to which it is dependent upon, the "network" appears to include "the sample, the additive, and the plurality of particles".

Claims 13-21 recite improper multiple dependent claims. Multiple dependent claims must recite so as to reflect dependency in the alternative form, i.e. "The method of any one of claims 1-12 wherein" or equivalent language.

Claim 14 is indeterminate in scope in reciting "wherein the sample includes white cells and platelets" because it fails specify what other elements are included in the sample.

Claim 15 is unclear by reciting "comprising measuring PSA". Acronyms or abbreviations must be recited at least one time in a set of claims.

Claim 16 is missing.

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Claim 17 is vague and indefinite in reciting "theoretically available cell depleted portion" because the term "theoretically" has no comparative basis for defining its metes and bounds. See also claim 21.

Claims 1-21 are objected to because of the following informalities: either claim 16 is missing or the claims are improperly numbered. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doshi et al. (US 5,766,552) in view of Kelland et al. (US 4,663,029).

Doshi et al. disclose a method for removing red blood cells from whole blood or a fraction thereof, by agglutinating whole blood with a mixture of antibodies (free agglutinating agents) and antibody coated particles (nucleating particles having agglutinating agents closely associated thereto) to form clusters of red blood cells. Agglutinating agents are coated onto particles, via conjugation or covalently binding into the particles, or otherwise associated to the particles so that each element is not separated from each other. Coated particles are prepared by mixing the particles with the agglutinating material to be used, maintaining the particles in contact with the agglutinating material for sufficient time to adsorb, absorb, conjugate, or coat the agglutinating agent to the surface of the particle, and then washing the particles to remove excess agglutinating agent (see column 5, lines 56-64). The combination of free agglutinating agents and nucleating particles coated with agglutinating agents provides for rapid and complete agglutination of red blood cells (see Summary and column 10, lines 8-12). Antibodies can be used as agglutinating agents having a binding affinity for a determinant present on the surface of the red blood cells. These antibodies are either monoclonal or polyclonal and reactive with any antigen i.e. PSA, present on the surface of the red blood cells such as major histocompatibility antigens cell surface proteins, cell surface carbohydrates, and cell surface glycoproteins (see column 7, line 66 bridging to column 8, line 16). Other agglutinating agents for red blood cells include polymeric amino acids such as polylysine, polyarginine, etc. (see column 8, lines 57-59).

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Ideally, the nucleating particles have an average size of 0.1 to 100 microns, preferably less than 10 microns in diameter, and are the same size or smaller than the red blood cells. The porous iron oxide particles are magnetizable polyacrolein beads (see column 8, line 61 to column 9, line 19). Doshi et al fails to teach the use of magnetic force in separating cell containing portion from cell depleted portion of whole blood into a vessel.

Kelland et al. disclose selective separation of particles according to particle magnetic susceptibility, independent of density, size, and shape of the particles (see Abstract). The Kelland-type separator has an elongated non-magnetic outer housing for receiving a slurry of magnetic and small susceptibility particles . A magnetic field is provided in the separation region which is oriented transversely to the longitudinal axes of parallel rods (see column 1 line 54 to column 2, line 25). In Kelland's teachings, particles in a slurry are continuously separated in accordance with their magnetic susceptibility and their size by passing the slurry through a separator comprising a non-magnetic canister having a generally rectangular inner cross section with relatively narrow space between opposing walls. A field extends a radial force on particles passing through the canister (see column 2 line 50 to column 3, line 6). The process is capable of handling high concentration slurry, eg. whole blood with red and white blood cells (see column 3, line 12-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the separator and method of magnetic separation as taught by Kelland et al. into the teachings of Doshi et al. in red blood cell separation because Doshi et al. specifically teach

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the use iron oxide particles in the form of magnetizable polyacrolein beads for use in complete agglutination or formation of RBC clusters and Kelland specifically teach the application of his method in separating cells attached to magnetic particles or beads as those taught by Doshi et al. One of ordinary skill in the art would have been motivated to complement the method of Doshi et al. in cellular separation using Kelland-type separator and technique because of the heightened level of selectivity achievable in separation of complex particle systems in incorporating the use of magnetic force as taught by Kelland et al.

Remarks

Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

Saur et al. (US 4,710,472) disclose a magnetic separation device suitable for removing magnetic bead coated cells from a system.

Hillman et al. (US 4,753,776) disclose a device and method for separating plasma from whole blood via filtering system with descending pore size to provide for successive removal of red blood cells without lysis.

Zuk (US 4,594,327) teaches a method for separating red blood cells from whole blood by combining the whole blood sample with a red blood cell binding agent and the mixture is filtered through a solid bibulous agent.

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Bernstein (US 5,169,789) discloses a device for solid phase immunodiffusion assay in which inhibitors for red blood cells are removed by adding adsorbent materials such as beads, antigen or antibody coated particles, before the ligand receptor assay can be performed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Patent Examiner
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JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER